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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,473	07/29/2003	Mark E. Deem	38349-0103H	9190
20985	7590	08/09/2005		
FISH & RICHARDSON, PC 12390 EL CAMINO REAL SAN DIEGO, CA 92130-2081			EXAMINER LEWIS, AARON J	
			ART UNIT 3743	PAPER NUMBER

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/630,473	DEEM ET AL.
Examiner	Art Unit	
AARON J. LEWIS	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 05/25/2005(AMENDMENT).

2a)  This action is FINAL.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1,5,6 and 9-13 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 1,5,6 and 9-13 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.  
\_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1,5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfernness et al. ('951) in view of Laufer et al. ('255).

As to claim 1, Alfernness et al. disclose a method for lung volume reduction (see abstract and col.2, lines 28-30), said method comprising: deploying an obstructive device (74 and fig.11) in a lung passageway to a lung tissue segment (col.4, lines 13-25); and aspirating the segment through the deployed obstructive device to at least partially collapse the lung segment (col.5, lines 18-30).

The difference between Alfernness et al. and claim 1 is deploying the obstructive device through an access catheter.

Laufer et al. teach using an access catheter (i.e. a bronchoscope (230)) having at least one working channel (figs.8 and 9) and a lens (col.8, line 12) for the purpose of visualizing a target treatment prior to positioning a treatment catheter (270) therethrough and precisely at the treatment site.

It would have been obvious to modify the manner of positioning the obstructive device of Alfernness et al. to include the introduction of the delivery catheter of Alfernness et al. into the working channel of a bronchoscope because it (i.e. the bronchoscope)

would have provided a means to enable medical personnel to view the target site prior to placement of the treatment device as taught by Laufer et al..

As to claim 5, Alfernness et al. as modified by Laufer et al. disclose a system for obstructing a lung passageway to a lung tissue segment, said system comprising: an access catheter (230 of Laufer et al.) having a proximal end, a distal end (figs.8,9 of Laufer et al.), and at least one lumen extending therethrough, and an obstruction device (74 of Alfernness et al.) deployable within the lung passageway having an inlet port adapted for aspirating (col.5, lines 18-20 and lines 26-30 of Alfernness et al.) the lung tissue segment through the inlet port, wherein the obstruction device is introduceable by the access catheter (230 of Laufer et al.).

3. Claims 6,13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfernness et al. ('951) in view of Laufer et al.('255) as applied to claims 1,5, above, and further in view of Daniel et al. ('455).

The difference between Alfernness et al. as modified by Laufer et al. and claim 6 is the incorporation of the obstruction device into a kit that also includes instructions for use according to a method of lung volume reduction.

Daniel et al. teach the incorporation of an obstruction device (e.g. endoscope) into a kit that also includes instructions for use (col.5, lines 30-38) for the purpose of providing medical personnel with both the equipment and instructions for performing surgical procedures within a patient's thoracic cavity using an endoscope.

It would have been obvious to further modify the obstruction device of Alfernness et al. to incorporate it into a kit and include instructions for performing surgical procedures

because it would have provided medical personnel with both the equipment and instructions for performing surgical procedures within a patient's chest cavity as taught by Daniel et al..

Claim 13 is substantially equivalent in scope to claim 6 and is included in Alferness et al. as modified by Laufer et al. and Daniel et al. for the reasons set forth above with respect to claim 6.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 9,10,12 are rejected under 35 U.S.C. 102(e) as being anticipated by Alferness et al. ('951).

As to claim 9, Alferness et al. disclose a method of lung volume reduction, said method comprising: releasing an obstructive device (74) in a lung passageway (50) to a

lung tissue segment; and aspirating (col.5, lines 18-20 and lines 26-30; col.6, lines 56-65 and col.4, lines 13-25) the segment through the released obstructive device to at least partially collapse the lung segment.

As to claim 10, Alferness et al. disclose a method for lung volume reduction, said method comprising: deploying an obstructive device (74) comprising a valve (90,100,110) in a lung passageway to a lung tissue segment; and aspirating (col.5, lines 18-20 and lines 26-30; col.6, lines 56-65 and col.4, lines 13-25) the segment through the deployed obstructive device to at least partially collapse the lung segment.

As to claim 12, Alferness et al. disclose a method for lung volume reduction, said method comprising: deploying an obstructive [device] (74) in a lung passageway to a lung tissue segment, and aspirating (col.5, lines 18-20 and lines 26-30; col.6, lines 56-65 and col.4, lines 13-25) the segment through the deployed obstructive device to at least partially collapse the lung segment.

#### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alferness et al. ('951) in view of Laufer et al. ('255).

The difference between Alferness et al. and claim 1 is deploying the obstructive device through an access catheter.

Laufer et al. teach using an access catheter (i.e. a bronchoscope (230)) having at least one working channel (figs.8 and 9) and a lens (col.8, line 12) for the purpose of visualizing a target treatment prior to positioning a treatment catheter (270) therethrough and precisely at the treatment site.

It would have been obvious to modify the manner of positioning the obstructive device of Alferness et al. to include the introduction of the delivery catheter of Alferness et al. into the working channel of a bronchoscope because it (i.e. the bronchoscope) would have provided a means to enable medical personnel to view the target site prior to placement of the treatment device as taught by Laufer et al..

***Claim Objections***

8. Claim 12 is objected to because of the following informalities: in line 2, the word –device— or an equivalent word appears to have been inadvertently omitted following "...obstructive..." but before "...in...". Appropriate correction is required.

***Response to Arguments***

9. Applicant's arguments with respect to claims 1,5,6,9-13 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



AARON J. LEWIS  
Primary Examiner  
Art Unit 3743

Aaron J. Lewis  
August 04, 2005